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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,635	02/09/2000	F. Abel Ponce de Leon	002076-033	2892

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/500,635	LEON ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003 and 29 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-25 and 27-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-25 27-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment to the specification filed 11-10-03 has been entered. The amendment to the claims filed 11-10-03 has not been entered because the status of claims 1-20 was not included.

However, the status of the claims in the amendment filed 12-29-03 is wrong. Claims 1-20 were cancelled in the amendment filed 2-19-02; claims 11-17 are not "Withdrawn" as stated in the amendment. To expedite prosecution, the amendment to the claims filed 12-29-03 has been entered. Claim 26 has been canceled.

Claims 21-25 and 27-35 are under consideration in the instant application.

Applicant's arguments filed 11-10-03 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 22 and 30 are objected to because "SCR" should be --SCF--.

Claim Rejections - 35 USC ' 112

1. Claims 21-25 and 27-32 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record.

Culturing PGCs in the absence of feeder cells and bFGF, SCF, LIF and IGF resulting in maintaining the PGCs for 14 days (claim 21) does not have support in the specification as originally filed for reasons of record.

Applicants point to pg 13, line 20, which states "while applicants cultured PGC in the absence of feeder cells, they further contemplate that feeder cells might also be useful." Applicants argue the specification, therefore, supports the phrase "absence of feeder cells." Applicants' argument does not address the thrust of the rejection. While pg 13, line 20, states applicants cultured PGCs in the absence of feeder cells, the citation implies that feeder cells may be required under some circumstances. The paragraph bridging pg 13-14 does not teach all PGCs mentioned in the specification, specifically PGCs maintained for 14 days, were cultured in the absence of feeder cells. The paragraph bridging pg 13-14 does not reasonably suggest that PGCs cultured in the absence of feeder cells were maintained for 14 days as claimed.

Applicants point to page 27, line 14, which states "[n]one of the cell feeder layers evaluated in this study improved the long term culture conditions of PGCs." It would have been unreasonable for one of skill to think that pg 27, line 14, meant that feeder cells were compared to the absence of feeder cells because the citation only discusses evaluating "the feeder layers" and did not discuss a culture without feeder layers was maintained for 14 days. Nor does the citation state "the feeder layers" were compared to the absence of feeder cells. In fact, pg 27 implies to one of skill in the art that

different types of feeder cells were compared with each other for their ability to culture PGCs long term, especially in context of the paragraph bridging pg 13-14 which discusses various potential types of feeder cells. Thus, one of skill could only reasonably conclude from pg 27, line 14, that different types of feeder layers were evaluated and compared in this study for their ability to improve long-term culture conditions of PGCs.

Overall, these two citations are the only ones in the specification that mention feeder cells. The specification does not teach the feeder cell conditions required to culture PGCs for 14 days. A generic statement that PGCs may be cultured without feeder cells does imply that PGCs maintained for 14 days were cultured in the absence of feeder cells, especially since pg 27 states in the first line under the heading "PGC culture conditions" that different feeder cells were used. The specification taken as a whole does not allow one of skill to reasonably conclude that PGCs maintained for 14 days were cultured in the absence of feeder cells. Therefore, the specification did not explicitly or implicitly describe using LIF, bFGF, SCF and ICF and the absence of feeder cells as claimed to maintain the culture of PGCs for 14 days as claimed.

Culturing PGCs in bFGF, SCF, LIF and IGF in the absence of feeder cells and sustaining the culture for 28 days or 4 months (claims 27-28) does not have support in the specification as originally filed for reasons of record. Applicants point to original claim 7 or 8. Applicants argument is not persuasive because the specification as

originally filed did not teach whether the presence or absence of feeder cells were required to maintain PGCs in culture for 28 days or 4 months as claimed.

Introducing a "nucleic acid that encodes a polypeptide and is functionally linked to gene expression regulatory sequences that are operable in an avian cell" into PGCs (claims 29 and 32) remains new matter. Applicants reiterate the argument that support is found on pg 17, lines 5-7 and 17-24. Applicants' argument is not persuasive. Pg 17, lines 5-7 and 17-24 only teaches introducing DNA encoding a polypeptide operably linked to regulatory sequences that function in avian cells. The phrase "gene expression regulatory sequences" cannot be found. The citation describes DNA encoding a polypeptide, not any nucleic acid as claimed. The citation describes the DNA as being under the regulatory control of sequences operable in avians, not "functionally linked to gene expression regulatory sequences."

2. Claims 21-25 and 27-35 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for culturing avian PGCs in the presence of LIF, bFGF, SCF and IGF and in the absence of feeder cells, does not reasonably provide enablement for one of skill to determine the feeder cell conditions essential to maintain cells for 14 days, 28 days or 4 months. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for reasons of record.

Claim 21 requires culturing avian PGCs in the presence of LIF, bFGF, SCF and IGF and in the absence of feeder cells for at least fourteen days. While the specification states feeder cells did not improve "long term culture" of the PGCs (pg 27, line 14), the specification does not teach the specific feeder cell conditions required to maintain PGCs for 14 days, 28 days or 4 months. The specification describes maintaining PGCs for 7 days (pg 22, line 4) and PGC clumps for up to four weeks (pg 22, line 7); however, the specification does not teach this was done in the absence of feeder cells. While the specification states PGCs were maintained for four months (pg 29, lines 23-24), the specification does not teach the feeder cell conditions used to maintain PGCs for 14 days, 28 days or 4 months as claimed.

Overall, two citations (pg 13-14 and pg 27-28) are the only ones in the specification that mention feeder cells. The specification does not teach the feeder cell conditions required to culture PGCs for 14 days, 28 days or 4 months. A generic statement that PGCs may be cultured without feeder cells does imply that PGCs maintained for 14 days were cultured in the absence of feeder cells, especially since pg 27 states in the first line under the heading "PGC culture conditions" that applicants used different types of feeder cells. The specification taken as a whole does not allow one of skill to reasonably conclude that PGCs maintained for 14 days were cultured in the absence of feeder cells. Therefore, the specification did not explicitly or implicitly describe using LIF, bFGF, SCF and ICF and the absence of feeder cells as claimed to

maintain the culture of PGCs for 14 days as claimed. The absence of guidance in the specification as to the specific feeder cell conditions required to maintain PGCs for 14 days is not considered an enabling disclosure for claims that require maintaining PGCs for 14 days under specific feeder cells conditions. Thus, it would have required one of ordinary skill in the art at the time the invention was made undue experimentation to determine the parameters required to culture PGCs in the absence of feeder cells as claimed.

Applicants point to page 27, line 14, which states "[n]one of the cell feeder layers evaluated in this study improved the long term culture conditions of PGCs." It would have been unreasonable for one of skill to think that pg 27, line 14, meant that feeder cells were compared to the absence of feeder cells because the citation only discusses evaluating "the feeder layers" and did not discuss a culture without feeder layers was maintained for 14 days. Nor does the citation state "the feeder layers" were compared to the absence of feeder cells. In fact, pg 27 implies to one of skill in the art that different types of feeder cells were compared with each other for their ability to culture PGCs long term, especially in context of the paragraph bridging pg 13-14 which discusses various potential types of feeder cells. Thus, one of skill could only reasonably conclude from pg 27, line 14, that different types of feeder layers were evaluated and compared in this study for their ability to improve long term culture conditions of PGCs.

Despite the fact that the specification states "no stable transfected cell line has been developed" (pg 30, line 8), given the teachings of Han, it would not have required one of skill undue experimentation to determine how to obtain and use the transfected PGCs of claims 29 and 32 for the purpose of observing the migration of PGCs in an embryo as taught by Han (see previous office action).

3. Claims 21-25 and 27-32 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

It is unclear how the phrase "at least the following growth factors in amounts sufficient to maintain said PGCs for at least fourteen days in tissue culture in the absence of feeder cells" contributes to claim 21. The claim already requires "culturing said PGCs for at least fourteen days in the absence of feeder cells in a culture medium comprising..:" LIF, bFGF, SCF and IGF. Applicants argue the phrase is present to make clear that the four factors are present but that other constituents may also be present. Applicants' argument is not persuasive. Deletion of the phrase "at least... ...feeder cells" still allows the medium to comprise (open language) LIF, bFGF, SCF and IGF as well as other constituents. Deletion of the phrase "at least... ...feeder cells" still leaves the limitation of culturing the PGCs in the absence of feeder cells for at least fourteen days at the beginning of (ii).

The scope of "maintenance" (preamble) and "culturing" (step ii, claim 21) are not commensurate in scope. The phrase "the maintenance" in the preamble should be changed to "culturing". Applicants statement that the preamble is consistent with step (ii) and that "[i]ndeed step (ii) recites culturing" does not address the rejection. Maintenance has a different scope than culturing.

Claim 22 remains grammatically unclear for reasons of record. Applicants state claim 22 is not grammatically incorrect and would be clear to the skilled artisan. Applicants' argument is not persuasive. The phrase "the concentrations... ...are at least the following minimal concentrations" is confusing, redundant and does not clearly set the minimal concentrations of the growth factors. Use of "at least" with "minimal" is redundant. The phrase –wherein said growth factors have a minimal concentration of:-- would overcome this rejection.

Claim 23 remains grammatically unclear for reasons of record. Applicants state claim 23 is not grammatically incorrect and would be clear to the skilled artisan. Applicants' argument is not persuasive. The phrase "the concentrations... ...said minimal concentrations" is confusing, redundant and does not clearly set the concentrations of the growth factors. Use of "at least" with "minimal" is redundant. The phrase --wherein said growth factors have a concentration in the range of from about two to one hundred times said minimal concentrations—would overcome this rejection.

Claim 29 remains grammatically unclear for reasons of record. Applicants state claim 29 is not grammatically incorrect and would be clear to the skilled artisan. Applicants' argument is not persuasive. The phrase step number should be (iii), not (iv). The "resultant PGCs" lack antecedent basis in claim 21. The phrase does not clear refer to the PGCs cultured for 14 days. The phrase "and is" is confusing and unnecessary. The phrase "introducing into the PGCs cultured for at least fourteen days a nucleotide sequence encoding a polypeptide functionally linked to gene expression regulatory sequences operable in an avian cell" would overcome this rejection.

The phrase "said culture being free of feeder cells and comprising medium comprising LIF, bFGF, SCF, and IGF" (claims 30 and 32) does not further limit the PGCs produced according to claim 21 which requires the PGCs be cultured in the presence of LIF, bFGF, SCF, and IGF and the absence of feeder cells. Applicants have not addressed this rejection.

Claim 32 remains grammatically unclear for reasons of record. Applicants state claim 21 is not grammatically incorrect and would be clear to the skilled artisan. Applicants' argument is not persuasive. The claim does not clearly refer to the PGCs cultured for 14 days. Reiteration of what was in the phrase is confusing and redundant. The phrase "wherein a nucleic acid has been introduced..." is confusing because does not clearly set forth the structure of the cells in the culture, i.e. that the cells comprise a nucleic acid sequence encoding a polypeptide functionally linked to regulatory

sequences that function in avian cells. The phrase is confusing because it cannot be determined if applicants are limiting the structure of the cells or adding a step to the method of claim 21. The phrase "A culture comprising avian PGCs maintained for at least fourteen days made by the method of claim 21, wherein said PGCs comprise a nucleotide sequence encoding a polypeptide functionally linked to gene expression regulatory sequences operable in an avian cell" would overcome this rejection.

Claim Rejections - 35 USC ' 102

4. Claims 21-25, 27, 28, 30 and 31 remain rejected under 35 U.S.C. 102(b) as being anticipated by Pain (7-25-96, Development, Vol. 122, pages 2339-2348, UnCover online at http://uncweb.carl.org/uncover/unchome.html) or in the alternative under 102 (a) as being anticipated by Pain (Aug. 1996, Development, Vol. 122, pages 2339-2348) and supported by Simkiss (1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137) for reasons of record.

Pain taught culturing avian blastodermal cells in complete media comprising bFGF, IGF, SCF and LIF in the absence feeder cells for 5 days (pg 2342, Fig. 2D), culturing PGCs for 160 days with bFGF, IGF, SCF and IGF in the presence of feeder cells (pg 2345, col. 2, line 10), and that "the cultures" were maintained with or without feeder cells (page 2341, col. 2, ¶ 4). Without evidence to the contrary, "the culture"

maintained for 160 days was maintained without feeder cells. The PGCs inherently form a monolayer as newly claimed because the culture conditions taught by applicants are identical to those taught by Pain. The avian blastodermal cells isolated from Stage X embryos of Pain have PGCs as claimed (Simkiss, pg 111, Fig. 4.1, top panel).

Applicants state Pain did not teach culturing avian PGCs in vitro in medium containing LIF, bFGF, SCF and IGF-1 for at least 14 days in the absence of feeder cells (pg 92nd to last ¶ of response). This statement is a reiteration from the last response and again is not considered an argument because it is not specific. All the limitations mentioned have been addressed in the rejection by the examiner, specifically that PGCs were maintained for 160 days with bFGF, IGF, SCF and IGF in the presence of feeder cells, and that "the cultures" were maintained with or without feeder cells. Applicants' statement does not specifically discuss the limitation that is missing from the reference.

Pain taught no less than the instant application. While Pain taught a preferred method of culturing cells included feeder cells (pg 2345, col. 2, line 10), and maintaining CECs for 160 days using feeder cells (pg 2345, col. 2, line 10), Pain did not teach culturing CEC for 160 days was limited to using feeder cells. Again, Pain taught "the cultures" were maintained with or without feeder cells (page 2341, col. 2, ¶ 4). Without evidence to the contrary, "the cultures" maintained without feeder cells includes "the culture" maintained for 160 days.

Claims 30 and 31, directed toward a culture made by the method described above, are anticipated by Pain. The culture described by Pain does not differ from the culture claimed. The culture of Pain has a combination of PGCs and EG cells. The method used to make the culture as claimed does not alter the structure or function of the culture so as to distinguish it from the culture of Pain. The method does not bear patentable weight in considering the art for claims 30 and 31 because it does not alter the structure or function of the culture.

Claim Rejections - 35 USC ' 103

5. Claims 21-25 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pain et al. (7-25-96, Development, Vol. 122, pages 2339-2348, UnCover online at http://uncweb.carl.org/uncover/unchome.html) or Pain et al. (Aug. 1996, Development, Vol. 122, pages 2339-2348) as supported by Simkiss (1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137) in view of Han et al. (Asian-Australasian Journal of Animal Sciences, (1994) Vol. 7, No. 3, pg 427-434) for reasons of record.

Pain taught culturing PGCs in complete media comprising bFGF, IGF, SCF and LIF in the absence feeder cells for 160 days (see 102 rejection above). Pain did not teach transfecting the PGCs with a nucleic acid sequence encoding a protein functionally linked to regulatory sequences as claimed.

However, Han taught PGCs transfected in vitro expressing RSVLTR/beta-G2 plasmid.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to culture PGCs using the method of Pain and transfect the PGCs using the method of Han. One of ordinary skill in the art at the time the invention was made would have been motivated to transfect the PGCs of Pain with a retrovirus as taught by Han because the purpose of Pain was to develop avian cells that can be transfected (pg 2339, col. 1, first ¶). One of ordinary skill in the art at the time the invention was made would have been motivated to transfect PGCs as taught by Han using the culture conditions of Pain to facilitate the proliferation of cells with an undifferentiated phenotype as suggested by Pain (pg 2345, col. 2, line 10).

Applicants' arguments regarding the 103 rejection are reiterated from the arguments regarding the 102 rejection. Applicants' arguments are not persuasive as discussed above in the 102 rejection. In addition, applicants argue Han does not cure the rejection. Applicants' argument is not persuasive because Han is being relied upon for introducing a vector encoding a protein operably linked to a promoter into PGCs as claimed.

Double Patenting

6. Claims 21-25, 30 and 31 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 10-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The limitation of culturing the PGCs for at least 14 days in claim 1 of '569 is equivalent to claim 26 in the instant application. Claims 1-5 and 10-12 of '569 are obvious species of claims 21-28, 30 and 31 in the instant application in that the claims of '569 require a "pure population" of avian PGCs while the instant claims encompass any avian PGCs. Claims 21-28, 30 and 31 in the instant application are obvious species of claims 1-5 and 10-12 of '569 because the claims in the instant application require the absence of feeder cells while the claims of '569 encompass the presence or absence of feeder cells. The claims of '569 do not specifically claim the "absence of feeded cells". However, the disclosure of '569 states PGCs may be cultured in the presence or absence of feeder cells. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to culture PGCs for 14 days as in the claims of '569 in the absence of feeder cells as in the disclosure of '569.

Applicants' willingness to provide a terminal disclaimer upon allowance was provided in the response filed 2-19-02, paper number 12.

However, applicants now provide new arguments.

Applicants argue the rejection is traversed because the claims of '569 do not require the absence of feeder cells. Applicants' argument is not persuasive. The rejection is based on the claims of '569 in view of the disclosure of '569 which states PGCs may be cultured in the presence or absence of feeder cells. If it is found that the instant application supports the limitation of the "absence of feeder cells," then disclosure of '569 supports the limitation as well. If it is found that the instant application supports the limitation, then the claims of '569 taken in context of the disclosure of '569 make the limitation of the "absence of feeder cells" as instantly claimed an obvious species of the claims of '569. The examiner has set forth both a double patenting rejection and new matter rejection, both of which are supported by solid reasoning.

7. Claims 21-25, 27, 28, 30 and 31 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 10-12 of U.S. Patent No. 6,156,569 (Dec. 5, 2000) in view of Pain (1996, Development, Vol. 122, pages 2239-2348) for reasons of record.

The scope of the claims in '569 and the instant application are discussed in the above rejection. The claims of '569 do not require maintaining the cells for at least 25 days or 4 months. However, Pain taught culturing avian embryonic cells for at least 160 days (page 2345, col. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed invention in '569 to maintain the PGCs for at least 25 days or 4 months. One of ordinary skill would have

been motivated to maintain the PGCs for at least 25 days or 4 months to increase the availability of the PGCs.

Applicants' willingness to provide a terminal disclaimer upon allowance was provided in the response filed 2-19-02, paper number 12.

Applicants' arguments regarding '569 are discussed above. Applicants' arguments regarding Pain are moot because they are not specific to any limitation.

8. Claims 21-25 and 27-32 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 10-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000 in view of Pain (1996, Development, Vol. 122, pages 2239-2348) and Han et al. (Asian-Australasian Journal of Animal Sciences, (1994) Vol. 7, No. 3, pg 427-434).

The scope of the claims in '569 and the instant application are discussed in the above rejection. The claims of '569 do not require maintaining the cells for at least 25 days or 4 months or transfecting the PGCs with a nucleic acid encoding a protein operably linked to regulatory sequences. However, Pain taught culturing avian embryonic cells for at least 160 days (pg 2345, col. 2) and Han taught transfecting PGCs in vitro with a nucleic acid sequence encoding a protein operably linked to regulatory sequences and obtaining expression of the protein. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed invention in '569 to maintain the PGCs for at least 25 days or 4 months.

One of ordinary skill would have been motivated to maintain the PGCs for at least 25 days or 4 months to increase the availability of the PGCs. One of ordinary skill in the art at the time the invention was made would have been motivated to transfect the PGCs with a retrovirus as taught by Han because the purpose of Pain was to develop avian cells that can be transfected (pg 2339, col. 1, first ¶). One of ordinary skill in the art at the time the invention was made would have been motivated to transfect PGCs as taught by Han using the culture conditions of Pain to facilitate the proliferation of cells with an undifferentiated phenotype as suggested by Pain (pg 2345, col. 2, line 10).

Applicants' arguments regarding Pain are moot because they are not specific to any limitation.

9. Claims 21-25 and 27-32 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 7, 8, 30, 31, 33-35, 37, 39, 40 and 43-46 of copending Application No. 09/127,624.

Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 21-28, 30 and 31 in the instant application are obvious species of claims 1-5 and 10-12 of '624 because the claims in the instant application require the absence of feeder cells while the claims of '624 encompass the presence or absence of feeder cells. Both require culturing PGCs in media comprising LIF, bFGF, SCF and IGF for at least fourteen days. It would have been obvious to culture PGCs as claimed in

'624 in view of the disclosure of '624, which taught culturing PGCs in the presence or absence of feeder cells.

This remains a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants argue the conflicting claims do not anticipate or render obvious the claimed prolonged PGC culture conditions effected [sic] in the absence of feeder cells. Applicants' argument is not persuasive because '624 has the same two citations discussing "feeder cells" as in the instant application. If the "absence of feeder cells" is supported in the instant application, it must be supported in '624 and would be an obvious species of the claims of '624.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

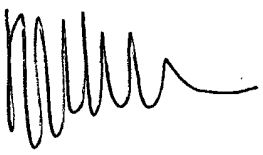
Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at 571-272-0738.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER